PATENT COOPERATION TREATY

# PCT

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

20 JUN 2005

| Applicant's or agent's file reference 710001 | FOR FURTHER ACTION | See Form PCT/IPEA/416 |
|---|---|---|
| International application No. PCT/AU2003/001714 | International filing date *(day/month/year)* 22 December 2003 | Priority date *(day/month/year)* 20 December 2002 |
| International Patent Classification (IPC) or national classification and IPC<br>**Int. Cl.** [7] A61M 35/00 | | |
| Applicant<br>ACRUX DDS PTY LTD (et al.) | | |

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 4 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. [X] *(sent to the applicant and to the International Bureau)* a total of 7 sheets, as follows:
      - [X] sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
      - [ ] sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.

   b. [ ] *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or table related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).
4. This report contains indications relating to the following items:

| | | |
|---|---|---|
| [X] | Box No. I | Basis of the report |
| [ ] | Box No. II | Priority |
| [ ] | Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| [ ] | Box No. IV | Lack of unity of invention |
| [X] | Box No. V | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| [ ] | Box No. VI | Certain documents cited |
| [ ] | Box No. VII | Certain defects in the international application |
| [ ] | Box No. VIII | Certain observations on the international application |

| Date of submission of the demand | Date of completion of the report |
|---|---|
| 16 July 2004 | 5 April 2005 |
| Name and mailing address of the IPEA/AU<br>AUSTRALIAN PATENT OFFICE<br>PO BOX 200, WODEN ACT 2606, AUSTRALIA<br>E-mail address: pct@ipaustralia.gov.au<br>Facsimile No. (02) 6285 3929 | Authorized Officer<br>**MATTHEW FORWARD**<br>Telephone No. (02) 6283 2606 |

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/AU2003/001714

**Box No. I Basis of the report**

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:

☐ international search (under Rules 12.3 and 23.1 (b))

☐ publication of the international application (under Rule 12.4)

☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the **elements** of the international application, this report is based on (*replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report*):

☐ the international application as originally filed/furnished

☒ the description:

pages **4-11** as originally filed/furnished
pages* **1,2,2a,3,3a** received by this Authority on **13 October 2004** with the letter of 13.10.04
pages* received by this Authority on with the letter of

☒ the claims:

pages as originally filed/furnished
pages* as amended (together with any statement) under Article 19
pages* **13,14** received by this Authority on **13.10.04** with the letter of 13.10.04
pages* received by this Authority on with the letter of

☒ the drawings:

pages **1/3-3/3** as originally filed/furnished
pages* received by this Authority on with the letter of
pages* received by this Authority on with the letter of

☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages
☐ the claims, Nos.
☐ the drawings, sheets/figs
☐ the sequence listing (*specify*):
☐ any table(s) related to the sequence listing (*specify*):

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

☐ the description, pages
☐ the claims, Nos.
☐ the drawings, sheets/figs
☐ the sequence listing (*specify*):
☐ any table(s) related to the sequence listing (*specify*):

* *If item 4 applies, some or all of those sheets may be marked "superseded."*

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/AU2003/001714

**Box No. V** **Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

| | | |
|---|---|---|
| Novelty (N) | Claims | YES |
| | Claims 1-9 | NO |
| Inventive step (IS) | Claims | YES |
| | Claims 1-9 | NO |
| Industrial applicability (IA) | Claims 1-9 | YES |
| | Claims | NO |

2. Citations and explanations (Rule 70.7)

The following documents identified in Australian Patent Office Search Report have been considered for the purposes of this report:

D1 GB 2054381

D2 WO 1991014467

D3 US 6485471

D4 US 4838857

D5 US 6213984

D6 WO 2003092773

D7 WO 2002058767

The document have also considered for the purposes of second report:

D8 WO 1994025090 A1 (HJERTMAN) 10 November 1994. Abstract,Fig.1-5, page5 line 27-page 18 line 28.

The new documents found for the purposes of third report:

D9 US 6142339 A (BLACKER ET AL.) 7 November 2000. Abstract, Fig.1-22.

D10 WO 1993024167 A1 (HOLROYD) 9 December 1993. Entire document.

D11 WO 2001037909 A1 (INGENJORSBYRA) 31 May 2001. Abstract, Fig.1-5.

D12 US 5421482 A (GARBY ET AL.) 6 June 1995. Abstract, Fig 1-7.

D13 US 5799651 A (GARBY ET AL.) 1 September 1998. Abstract, Fig.1-7.

D14 US 2966175 A (HYDE) 27 December 1960. Entire document.

Present claims define a substance dispensing device being configured to indicate the extent to which substance has been dispensed therefrom, the device including: a substance storage container for containing substance to be dispensed; a pump, each operation of the pump dispensing a predetermined percentage of the substance stored in the container; and an actuator that is biased towards a rest position and is moved from the rest position to effect each operation of the pump and return to the rest position to enable subsequent operations of the pump; and a usage indicator having a movable member responsive to each operation of the pump, indicator means associated with the movable member providing a visual indication of the extent to which substance has been dispensed from the container.

**Supplemental Box**

**In case the space in any of the preceding boxes is not sufficient.**

Continuation of: Box no V

NOVELTY (N): Claims 1-9

D4 discloses a medication device with control mechanism associated with the sensor and the timing device, actuates the receptacle to expel its contents at a controlled rate over the selected period of time. Claim 1 lack of novelty and inventive step in view of D4 as D4 discloses all and every technical features of claim 1. Dependent claims 2-9 are ether disclosed in D4 or constitute obvious variation in view of common general knowledge.

D14 discloses a motor-driven syringe for use in the accurate volumetric delivery of liquids with antibacklash spring (25) and motor assembly which is "an actuator that is biased towards a rest position and is moved from the rest position to effect each operation of the pump and return to the rest position to enable subsequent operation of the pump". D14 discloses an electric type counter (15) which provides visible indication of the extent to which substance has been dispensed from the container. D14 discloses mechanically operated electric switch (47) having direct mechanical connection with the driving system for the syringe which is movable member of usage indicator responsive to each operation of the pump. Claim 1 lack of novelty and inventive step in view of D14 as D14 discloses all and every technical features of claim 1. Dependent claims 2-9 are ether disclosed in D4 or constitute obvious variation in view of common general knowledge.

INVENTIVE STEP:

D9 discloses aerosol dispenser for dispensing metered dosages of medicaments from a container having a valve stem extending longitudinally therefrom and moveable between an open and closed position; the container is reciprocally moveable within the housing along a longitudinal axis; an indicator member includes dosage indicia visible to a user and circular gear - which is a "substance dispensing device being configured to indicate the extent to which substance has been dispensed therefrom, the device including: a substance storage container for containing substance to be dispensed; and an actuator that is biased towards a rest position and is moved from the rest position to effect each operation of the pump and return to the rest position to enable subsequent operations of the pump; and a usage indicator having a movable member responsive to each operation of the pump, indicator means associated with the movable member providing a visual indication of the extent to which substance has been dispensed from the container. D9 does not disclose a pump, each operation of the pump dispensing a predetermined percentage of the substance stored in the container. D1 discloses a substance dispensing device with the pump dispensing a predetermined percentage of the substance stored in the container. Claim 1 does not involve inventive step in view of D1 and D9.

D10 – D13 disclose all technical features of claim 1 except the technical feature "pump, each operation of the pump dispensing a predetermined percentage of the substance stored in the container". That feature is disclosed in D1 – D7. Claim 1 does not involve inventive step in view of D1 - D7 and D10 - D13.

Dependent claims 2-9 do not involve inventive step in view of D1 - D13 and common general knowledge.

# USAGE INDICATOR

This invention relates to means for indicating the extent to which a device has been used. The invention has particular, but not exclusive, application to devices for dispensing a substance, such as a pharmaceutical, medicinal, or therapeutic substance. It will be convenient to hereinafter describe the invention with reference to such dispensing devices intended for transdermal and/or percutaneous delivery of substances, but it is to be understood that the invention has broader application.

It is usually the case that substance dispensing devices of the foregoing kind can be used on several occasions before the quantity of the substance stored in the device is exhausted. It is also a common requirement that an accurately metered amount of the substance is dispensed each time the device is operated.

Devices of the foregoing kind have been provided with means that enable the user to determine when the stored quantity of the substance is getting low. Various different arrangements have been provided for that purpose, but they have not been entirely satisfactory because of cost, lack of accuracy, or difficulty to read or interpret.

Another problem encountered with devices of the foregoing kind is the possibility of the device dispensing less than the intended quantity of the substance. That may occur because of inadequate care on the part of the operator, and may also occur because the stored quantity of the substance remaining in the device is too small at the time the device is operated.

It is an object of the present invention to provide a relatively inexpensive, accurate and easy to read usage indicator. It is a further object of the present invention to provide a substance dispensing device including such an indicator. Still another object of the invention is to provide a substance dispensing device having a usage indicator, and also having means preventing operation of the device when the quantity of the stored substance approaches exhaustion.

According to the present invention there is provided a substance dispensing device being configured to indicate the extent to which substance has been dispensed therefrom, the device including:

a substance storage container for containing substance to be dispensed;

a pump, each operation of the pump dispensing a predetermined percentage of the substance stored in the container; and

an actuator that is biased towards a rest position and is moved from the rest position to effect each operation of the pump and return to the rest position to enable subsequent operations of the pump; and

a usage indicator having a movable member responsive to each operation of the pump, indicator means associated with the movable member providing a visual indication of the extent to which substance has been dispensed from the container. The movable member is moved in response to movement of the actuator away from its rest position. It is also preferred that the movable member is moved in response to movement of the actuator back to its rest position, so that two stage movement of the movable member represents a single operation of the pump.

It is preferred that the actuator is moved in the direction of an axis and the movable member is rotated about the axis, the actuator having drive means that cooperates with reaction means of the movable member to convert the axial movement of the actuator to rotational movement of the movable member about the axis. Preferably the drive means includes a pair of axially spaced lugs formed with the actuator and the reactive means includes two series of teeth formed with the movable member one series for each lug, the lugs being spaced axially so that only one lug can engage a tooth of its respective series of teeth at any one time.

It is preferred that the number of teeth in either series is selected according to the number of operations of the pump required to substantially exhaust the substance from its container. It is also preferred that the movable member is a first movable member and the usage indicator includes a second

movable member, the second movable member cooperating with the first movable member to move only after the first movable member has completed one revolution, whereby complete revolution of both first and second movable members represents the number of operations of the pump required to substantially exhaust substance from the container. It is further preferred that the device include an interlock means cooperable with the usage indicator being activated after a predetermined number of operations of the pump to prevent

further operation of the pump. Preferably the device includes a hollow body for accommodating the container, the pump and usage indicator, the body having an aperture through which the indicator means is viewed.

It will be convenient to hereinafter describe the invention in greater detail by reference to the accompanying drawings showing an example embodiment of the invention. The particularity of the drawings and the related description of those drawings is not to be understood as superseding the generality of the definition of the invention as provided in the claims. The drawings show the usage indicator of the invention associated with a substance dispensing device.

Figure 1 illustrates in cross section a substance dispensing device.

Figure 2 illustrates a side elevation of a housing for the dispensing device.

Figure 3 illustrates an exploded view of the substance dispensing device and housing.

Figures 4 – 8 illustrate in diagnostic form the manner in which lug of an actuator button co-operate with teeth of a usage indicator.

Figure 9 illustrates a front elevation of the actuator button including the lugs.

Figure 1 shows an example substance dispensing device 1 associated with a usage indicator 2 according to one embodiment of the invention. The device 1 includes a substance storage container 3 and a pump 4 operable to pressurise the contents of the container 3 and thereby induce a quantity of the substance to be expelled through a nozzle 5, possibly in the form of a spray or mist. The pump 4 may be of a known kind that operates in a known manner in response to downward movement of the nozzle head 6 of the pump 4. In the particular arrangement shown, an actuator button 7 overlies the head 6 and cooperates with that head so that depression of the button 7 causes downward movement of the head 6. An opening 8 formed through a side wall of the button 7 is aligned with the nozzle 5 so as to allow passage of the substance expelled through the nozzle 5.

It is to be understood that the usage indicator 2 could be used with other types of dispensing devices, including aerosol-type dispensers.

In the arrangement shown by Figure 1, the usage indicator 2 is located between two supports or retainers 9 and 10 that hold the indicator 2 against

movement with the actuator button 7. The retainers 9 and 10 can be of any suitable form or construction. As hereinafter described in greater detail, the usage indicator 2 responds to operational movement of the actuator button 7 so as to indicate the extent to which the device 1 has been used.

Figure 1 shows the button 7 in a rest position. Downward movement of the button 7 from that rest position causes operation of the pump 4, and it is preferred that biasing means functions to return the button 7 to the rest position when downward pressure is removed from the button 7. It is further preferred that the usage indicator 2 responds to downward movement of the button 7

CLAIMS

1. A substance dispensing device being configured to indicate the extent to which substance has been dispensed therefrom, the device including:

a substance storage container for containing substance to be dispensed;

a pump, each operation of the pump dispensing a predetermined percentage of the substance stored in the container; and

an actuator that is biased towards a rest position and is moved from the rest position to effect each operation of the pump and return to the rest position to enable subsequent operations of the pump; and

a usage indicator having a movable member responsive to each operation of the pump, indicator means associated with the movable member providing a visual indication of the extent to which substance has been dispensed from the container.

2. A substance dispensing device according to claim 1 wherein the movable member is moved in response to movement of the actuator away from its rest position.

3. A substance dispensing device according to claim 2, wherein the movable member is moved in response to movement of the actuator back to its rest position, so that two stage movement of the movable member represents a single operation of the pump.

4. A substance dispensing device according to claim 3, wherein the actuator is moved in the direction of an axis and the movable member is rotated about the axis, the actuator having drive means that cooperates with reaction means of the movable member to convert the axial movement of the actuator to rotational movement of the movable member about the axis.

5. A substance dispensing device according to claim 4, wherein the drive means includes a pair of axially spaced lugs formed with the actuator and the reactive means includes two series of teeth formed with the movable member

one series for each lug, the lugs being spaced axially so that only one lug can engage a tooth of its respective series of teeth at any one time.

6. A substance dispensing device according to claim 5, wherein the number of teeth in either series is selected according to the number of operations of the pump required to substantially exhaust the substance from its container.

7. A substance dispensing device according to claim 6, wherein the movable member is a first movable member and the usage indicator includes a second movable member, the second movable member cooperating with the first movable member to move only after the first movable member has completed one revolution, whereby complete revolution of both first and second movable members represents the number of operations of the pump required to substantially exhaust substance from the container.

8. A substance dispensing device according to any one of the preceding claims, including an interlock means cooperable with the usage indicator being activated after a predetermined number of operations of the pump to prevent further operation of the pump.

9. A substance dispensing device including a hollow body for accommodating the container, the pump and usage indicator, the body having an aperture through which the indicator means is viewed.

# USAGE INDICATOR

This invention relates to means for indicating the extent to which a device has been used. The invention has particular, but not exclusive, application to devices for dispensing a substance, such as a pharmaceutical, medicinal, or therapeutic substance. It will be convenient to hereinafter describe the invention with reference to such dispensing devices intended for transdermal and/or percutaneous delivery of substances, but it is to be understood that the invention has broader application.

It is usually the case that substance dispensing devices of the foregoing kind can be used on several occasions before the quantity of the substance stored in the device is exhausted. It is also a common requirement that an accurately metered amount of the substance is dispensed each time the device is operated.

Devices of the foregoing kind have been provided with means that enable the user to determine when the stored quantity of the substance is getting low. Various different arrangements have been provided for that purpose, but they have not been entirely satisfactory because of cost, lack of accuracy, or difficulty to read or interpret.

Another problem encountered with devices of the foregoing kind is the possibility of the device dispensing less than the intended quantity of the substance. That may occur because of inadequate care on the part of the operator, and may also occur because the stored quantity of the substance remaining in the device is too small at the time the device is operated.

It is an object of the present invention to provide a relatively inexpensive, accurate and easy to read usage indicator. It is a further object of the present invention to provide a substance dispensing device including such an indicator. Still another object of the invention is to provide a substance dispensing device having a usage indicator, and also having means preventing operation of the device when the quantity of the stored substance approaches exhaustion.

According to the present invention there is provided ~~a substance~~ dispensing device being configure to indicate the extent to which substance has been dispensed therefrom, the device ~~including~~:

a substance storage container for containing substance to be dispensed;

a pump, each operation of the pump dispensing a predetermined percentage of the substance stored in the container; and

a usage indicator having a movable member responsive to each operation of the pump, indicator means associated with the movable member providing a visual indication of the extent to which substance has been dispensed from the device.

Preferably the device includes an actuator that is moved from a rest position to effect each operation of the pump and return to the rest position to enable further operation of the pump, the movable member being moved in response to movement of the actuator away from its rest position. It is also preferred that the movable member is moved in response to movement of the actuator back to its rest position, so that two stage movement of the movable member represents a single operation of the pump.

It is preferred that the actuator is moved in the direction of an axis and the movable member is rotated about the axis, the actuator having drive means that cooperates with reaction means of the movable member to convert the axial movement of the actuator to rotational movement of the movable member about the axis. Preferably the drive means includes a pair of axially spaced lugs formed with the actuator and the reactive means includes two series of teeth formed with the movable member one series for each lug, the lugs being spaced axially so that only one lug can engage a tooth of its respective series of teeth at any one time.

It is preferred that the number of teeth in either series is selected according to the number of operations of the pump required to substantially exhaust the substance from its container. It is also preferred that the movable member is a first movable member and the usage indicator includes a second movable member, the second movable member cooperating with the first movable member to move only after the first movable member has completed one revolution, whereby complete revolution of both first and second movable members represents the number of operations of the pump required to substantially exhaust substance from the container. It is further preferred that the device include an interlock means cooperable with the usage indicator being activated after a predetermined number of operations of the pump to prevent

further operation of the pump. Preferably the device includes a hollow body for accommodating the container, the pump and usage indicator, the body having an aperture through which the indicator means is viewed.

It will be convenient to hereinafter describe the invention in greater detail by reference to the accompanying drawings showing an example embodiment of the invention. The particularity of the drawings and the related description of those drawings is not to be understood as superseding the generality of the definition of the invention as provided in the claims. The drawings show the usage indicator of the invention associated with a substance dispensing device.

Figure 1 shows an example substance dispensing device 1 associated with a usage indicator 2 according to one embodiment of the invention. The device 1 includes a substance storage container 3 and a pump 4 operable to pressurise the contents of the container 3 and thereby induce a quantity of the substance to be expelled through a nozzle 5, possibly in the form of a spray or mist. The pump 4 may be of a known kind that operates in a known manner in response to downward movement of the nozzle head 6 of the pump 4. In the particular arrangement shown, an actuator button 7 overlies the head 6 and cooperates with that head so that depression of the button 7 causes downward movement of the head 6. An opening 8 formed through a side wall of the button 7 is aligned with the nozzle 5 so as to allow passage of the substance expelled through the nozzle 5.

It is to be understood that the usage indicator 2 could be used with other types of dispensing devices, including aerosol-type dispensers.

In the arrangement shown by Figure 1, the usage indicator 2 is located between two supports or retainers 9 and 10 that hold the indicator 2 against movement with the actuator button 7. The retainers 9 and 10 can be of any suitable form or construction. As hereinafter described in greater detail, the usage indicator 2 responds to operational movement of the actuator button 7 so as to indicate the extent to which the device 1 has been used.

Figure 1 shows the button 7 in a rest position. Downward movement of the button 7 from that rest position causes operation of the pump 4, and it is preferred that biasing means functions to return the button 7 to the rest position when downward pressure is removed from the button 7. It is further preferred that the usage indicator 2 responds to downward movement of the button 7

CLAIMS

1. A substance dispensing device being configured to indicate the extent to which substance has been dispensed therefrom, the device including:

a substance storage container for containing substance to be dispensed;

a pump, each operation of the pump dispensing a predetermined percentage of the substance stored in the container; and

a usage indicator having a movable member responsive to each operation of the pump, indicator means associated with the movable member providing a visual indication of the extent to which substance has been dispensed from the container.

2. A substance dispensing device according to claim 1 including an actuator that is moved from a rest position to effect each operation of the pump and return to the rest position to enable further operation of the pump, the movable member being moved in response to movement of the actuator away from its rest position.

3. A substance dispensing device according to claim 2, wherein the movable member is moved in response to movement of the actuator back to its rest position, so that two stage movement of the movable member represents a single operation of the pump.

4. A substance dispensing device according to claim 3, wherein the actuator is moved in the direction of an axis and the movable member is rotated about the axis, the actuator having drive means that cooperates with reaction means of the movable member to convert the axial movement of the actuator to rotational movement of the movable member about the axis.

5. A substance dispensing device according to claim 4, wherein the drive means includes a pair of axially spaced lugs formed with the actuator and the reactive means includes two series of teeth formed with the movable member one series for each lug, the lugs being spaced axially so that only one lug can engage a tooth of its respective series of teeth at any one time.

6. A substance dispensing device according to claim 5, wherein the number of teeth in either series is selected according to the number of operations of the pump required to substantially exhaust the substance from its container.

7. A substance dispensing device according to claim 6, wherein the movable member is a first movable member and the usage indicator includes a second movable member, the second movable member cooperating with the first movable member to move only after the first movable member has completed one revolution, whereby complete revolution of both first and second movable members represents the number of operations of the pump required to substantially exhaust substance from the container.

8. A substance dispensing device according to any one of the preceding claims, including an interlock means cooperable with the usage indicator being activated after a predetermined number of operations of the pump to prevent further operation of the pump.

9. A substance dispensing device including a hollow body for accommodating the container, the pump and usage indicator, the body having an aperture through which the indicator means is viewed.